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Poster presentation

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Tipranavir in highly ARV-experienced patients: efficacy and tolerability results from the French prospective NADIS cohort

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Purpose of the study

To assess week 12 virologic efficacy and tolerability of tipranavir (TPV) in a cohort of French HIV-infected patients.

Methods

Prospective cohort of French HIV-infected patients. Data were collected from September 2003 in extended access program and after TPV was licensed (December 2005) in seven clinical units using Nadis electronic medical record databases.

Summary of results

On November 1, 2007, 207 patients have been treated with TPV: median age 44 years [40–50], 48% stage C, 81% male, 43% MSM, 28% co-infected (72% HIV/HCV), median HIV infection duration 15 years [12–18]. Median nadir of CD4 cell counts was 53/mm3 [11–113], and zenith of HIV-RNA was 5.6 log cp/mL [5–5.9].

At baseline, CD4 cell count and HIV-RNA were 153/mm3 [65–279] and 4.6 log cp/mL [3.8–5.2], respectively. Resistance mutations testing is available in 94 patients infected with a sub-type B virus: 71/94 patients have no resistance to TPV according the ANRS algorithm 2008. All the patients were ARV-experienced, with a median antiretroviral treatment duration of 10 years [IQR 9–12], 11 previous ARV regimens [7–15] including eight PI-including regimens [5–11], an LPV exposure of 24 months [6–40] and three PI-containing treatment interruption for virologic failure [2–6]. TPV initiation is due to virologic failure of the previous regimen in 75% of the cases. TPV/r was most often combined with two NRTIs + ENF (31%). TPV/r was associated with ENF in 63% of the patients in whom 80% were ENF-naïve.

At week 12, HIV-RNA was below 200 cp/mL in 53.5% of patients. Median increase in CD4 cell count was 53/mm3 [5–115]. TPV/r was stopped in 69% of the patients after median treatment duration of 66 weeks mainly for treatment failure (46%) or adverse events (29%) including hepatitis toxicity (10%) and GI disturbance (8%). Grade 3–4 hepatic cytolysis (ALAT>5 N) occurred in 13 patients (6%).

Conclusion

In this highly treatment-experienced patient population, more than 50% of the patients reached <200 copies/mL at week 12; and 42 patients stopped TPV/r for adverse events. TPV/r-containing regimens can be a valuable option in this highly ARV-experienced population.